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08/541,191	10/11/1995	JON F. KAYYEM	A-62629/RFT	9939

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EXAMINER	
JONES, DAMERON LEVEST	
ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/541,191	Applicant(s) KAYYEM ET AL.	
	Examiner D. L. Jones	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of Paper No. 33, filed 7/12/02, wherein an acceptable terminal disclaimer was filed along with a request for a continue prosecution application (CPA) were submitted.

Note: Claims 1-22 are pending.

RESPONSE TO APPLICANT'S ARGUMENTS

2. The Applicant's arguments filed 7/12/02 (Paper No. 33) to the rejection of claims 1-22 made by the Examiner under 35 USC 103 and/or double patenting have been fully considered and deemed persuasive for reasons of record. Therefore, the said rejections are hereby withdrawn.

NEW GROUNDS OF REJECTIONS

112 First Paragraph Rejection

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for (a) Gd-DTPA-PDL/Tf-PLL/DNA, (b) DNA/Tf/Gd-DTPA/PL, and (c) PLL/Tf-PLL/DNA, does not reasonably provide enablement for all combinations comprising (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court in *In re Wands* (8 USPQ2d 1400 (CAFC 1986)). These factors are (1) nature of the invention; (2) state of the prior art; (3) level of one of ordinary skill in the art; (4) level of predictability in the art; (5) amount of direction and guidance provided by the inventor; (6) existence of working examples; (7) breadth of claims; and (8) quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(1) Nature of the invention

The claims are directed to delivery vehicles and methods of delivering physiological agents and a nucleic acid comprising various combinations of (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule.

(2) State of the prior art

The references do not indicate the specific combinations that useful with the claimed invention. Likewise, the references do not indicate which delivery vehicles and methods comprising (1) a first polymeric molecule; (2) at least one second polymeric

molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule are compatible with the instant invention.

(3) Level of one of ordinary skill in the art

The level of one of ordinary skill in the art is high. Independent claims 1, 16, 17, and 22 encompass a vast number of possible combinations comprising (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule. Applicant's specification does not enable the public to make or use such a vast number of possible combinations.

(4) Level of predictability in the art

The art pertaining to the deliver vehicles and methods of delivering nucleic acids and physiological agents is highly unpredictable. Determining the various combinations of (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule requires various experimental procedures and without guidance that is applicable to all delivery vehicles and methods of delivering nucleic acids and physiological agents, there would be little predictability in performing the claimed invention.

(5) Amount of direction and guidance provided by the inventor

Independent claims 1, 16, 17, and 22 encompass a vast number of compositions comprising (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule. Applicant's limited guidance does not enable the public to prepare such numerous combinations. There is no directional guidance for which components are compatible in generating a productive delivery vehicle or use of a vehicle in a delivery method. Hence, there is no enablement for all possible permutations and combinations of the delivery vehicle components.

(6) Existence of working examples

Independent claims 1, 16, 17, and 22 encompass a vast number of delivery vehicle components. Applicant's limited working examples do not enable the public to prepare and use such a numerous amount of delivery vehicle combinations. While Applicant's claims encompass a plethora of possible delivery vehicle component combinations, the specification provides a limited number of species (e.g., Gd-DTPA-PDL/Tf-PLL/DNA, (b) DNA/Tf/Gd-DTPA/PL, and (c) PLL/Tf-PLL/DNA).

(7) Breadth of claims

The claims are extremely broad due to the vast number of possible (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule combinations.

(8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure

The specification does not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with the claims. In particular, the specification fails to enable the skilled artisan to practice the invention without undue experimentation. Furthermore, based on the unpredictable nature of the invention, the state of the prior art, and the extreme breadth of the claims, one skilled in the art could not perform the claimed invention without undue experimentation.

112 Second Paragraph Rejection

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-22: The claims as written are ambiguous because one cannot readily ascertain what is being claimed. Specifically, the claims as written read on various combinations comprising (1) a first polymeric molecule; (2) at least one second polymeric molecule; (3) at least one cell targeting moiety; (4) a third polymeric molecule; (5) a nucleic acid; (6) at least one first polycationic molecule; (7) at least one contrast agent; and/or (8) a second polycationic molecule. However, one of ordinary skill in the art would not be able to ascertain what is encompassed in the claims as written due to

the components that may be present. Applicant is respectfully requested to clarify the claims in order that one may determine what is being claimed.

COMMENTS/NOTES

7. It should be noted that Gd-DTPA-PDL/Tf-PLL/DNA, (b) DNA/Tf/Gd-DTPA/PL, and (c) PLL/Tf-PLL/DNA have been searched. These are the species for which Applicant is enabled as set forth above. Thus, the enabled species have been searched and found allowable over the prior art of record because the prior art neither anticipates nor renders obvious the specific combinations of polymeric molecule(s), cell targeting moiety/a nucleic acid, and contrast agent.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

D. L. Jones
Primary Examiner
Art Unit 1616

March 30, 2004